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EXAMINER

ELVE, MARIA ALEXANDRA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 7-8, 11-17 & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acciai et al. (USPN 5,855,802) in view of Pacetti et al. (USPN 6,695,920), McCoy (USPAP 2003/0234243 A1) and Applicant's Admitted Prior Art (AAPA).

Acciai et al. discloses a method and apparatus for forming a tubular article having a perforated annular wall, such as a surgical stent. Figure 3 shows a laser (40), a fiber optic (44), a beam splitter (42) and an optical guide (46). Note that the laser beam moves partially in a horizontal direction in the fiber optic and horizontally in the optical guide. The tubular member (32) is mounted in a chuck (34). The laser beams are focused by focusing mirrors (56 & 58) mounted at 45° (tuning mirror). The apparatus is supported by a precision table (66) and a table (68). The tubular member is rotated by a rotating means (36), powered by a rotary drive motor (38). The tubular member is moved in a horizontal (translational) direction by means of a linear drive motor (70). The laser beams (60 & 62) cut the tubular member, in this case a stent.

Acciai et al. does not teach all the elements mounted to one table, the coupling of the linear and rotary motors, the presence of guides, the workpiece below the motor(s), the direct cutting using the laser, or the use of a coolant.

Pacetti et al. discloses a mandrel apparatus for supporting a stent. The stent is connected to a rotational motor (24) and another motor (28), which provides linear directional motion (back and forth along a rail). In addition, gear members (22) (guides) and a rail (30) provide guide members.

It would have been obvious to one of ordinary skill in the art at the time of the invention to couple the motor(s) and provide guides (gear members for stent support and rails), as taught by Pacetti et al. in the Acciai et al. system because coupling the motors minimizes manufacturing real estate and guides support components and provides articles for motion.

McCoy discloses a multi-axis laser apparatus for the fine cutting of tubing (i.e. the making of stents). Tubes are affixed under a laser and positioned using a computer-generated signal in order to move the tube in a very intricate and precise pattern around a linear and rotary axis. A water system is incorporated in the apparatus to remove **debris falling** into the interior of the cut tube and to push discrete portions of the cut tube (or stents) into a parts catcher to separate the stent from the uncut portion of the tube. The tubing is feed by reciprocal relative movement through a cutting block by a collet relative to the clamp, which positions a finite length of the tubing beneath the beam. The pattern cut is controlled by movement of the tubing relative to the beam simultaneously along an X (length) and Y axis (rotary) controlled by a computerized

Art Unit: 3742

encoder as part of a CNC positioning equipment. A computer software controlled rotary and linear movement subassembly apparatus. The cutting of the tubing is conducted on an x-axis table, which has a combination of rotary (y-axis) and linear (x-axis) movements of the tubing relative to the cutting laser beam. (abstract, figures, 0017, 0019, 0025, 0028, 0033)

McCoy discloses:

The present invention provides an improved system for producing metal stents with a fine precision structure cut from a small diameter, thin-walled, cylindrical tube. The tubes are fixtured under a laser and positioned utilizing a computer generated signal to move the tube in a very intricate and precise pattern around a linear and rotary axis. The stent is cut from small diameter tubing held between a collet and clamp, one of which is periodically opened and the other reciprocally moved to position a small length of tubing, sequentially beneath the cutting head. A water system is incorporated in the apparatus to remove debris falling into the interior of the cut tube and to push discrete portions of the cut tube (or stents) into a parts catcher to separate the stent from the uncut portion of the tube. (abstract)

...a gas jet stream substantially surrounds the laser beam where the beam impinges on the working outer tube surface to aid in cutting said tubing. (claim 7)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a laser directly and use a coolant as taught by McCoy in the Acciai et al. apparatus and process because direct laser cutting while enhance efficiency and the coolant would yield greater precision because the debris would be removed during the laser machining.

Art Unit: 3742

It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time of the invention to place the stent and its associated "machining" debris at the bottom of the apparatus because this would negate contamination and possible damage to apparatus parts. For example this configuration would prevent chips from falling into motor windings and so forth.

Making elements integral was held to have been obvious. In re Wolfe 116 USPQ 443. Reversal of parts was held to have been obvious. In re Gazda 104 USPQ 400. Rearrangement of parts was held to have been obvious. In re Japikse 86 USPQ 70.

AAPA includes a description of a laser/water jet hybrid made by SYNOVA Inc. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the SYNOVA hybrid laser/water system because it would ensure precision machining of the stent by removing cutting debris.

Claims 1, 5, 7-8, 11-17 & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acciai et al. (USPN 5,855,802) in view of Pacetti et al. (USPN 6,695,920), McCoy (USPAP 2003/0234243 A1) and Kranz (USPN 6,197,047).

Acciai et al. discloses a method and apparatus for forming a tubular article having a perforated annular wall, such as a surgical stent. Figure 3 shows a laser (40), a fiber optic (44), a beam splitter (42) and an optical guide (46). Note that the laser beam moves partially in a horizontal direction in the fiber optic and horizontally in the optical guide. The tubular member (32) is mounted in a chuck (34). The laser beams are focused by focusing mirrors (56 & 58) mounted at 45° (tuning mirror). The apparatus is

Art Unit: 3742

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Acciai et al. does not teach all the elements mounted to one table, the coupling of the linear and rotary motors, the presence of guides, the workpiece below the motor(s), the direct cutting using the laser, or the use of a coolant.

Pacetti et al. discloses a mandrel apparatus for supporting a stent. The stent is connected to a rotational motor (24) and another motor (28), which provides linear directional motion (back and forth along a rail). In addition, gears members (22) (guides) and a rail (30) provide guide members.

It would have been obvious to one of ordinary skill in the art at the time of the invention to couple the motor(s) and provide guides (gear members for stent support and rails), as taught by Pacetti et al. in the Acciai et al. system because coupling the motors minimizes manufacturing real estate and guides support components and provides articles for motion.

McCoy discloses a multi-axis laser apparatus for the fine cutting of tubing (i.e. the making of stents). Tubes are affixed under a laser and positioned using a computer-generated signal in order to move the tube in a very intricate and precise pattern around a linear and rotary axis. A water system is incorporated in the apparatus to remove **debris falling** into the interior of the cut tube and to push discrete portions of the cut tube (or stents) into a parts catcher to separate the stent from the uncut portion of the

Art Unit: 3742

tube. The tubing is feed by reciprocal relative movement through a cutting block by a collet relative to the clamp, which positions a finite length of the tubing beneath the beam. The pattern cut is controlled by movement of the tubing relative to the beam simultaneously along an X (length) and Y axis (rotary) controlled by a computerized encoder as part of a CNC positioning equipment. A computer software controlled rotary and linear movement subassembly apparatus. The cutting of the tubing is conducted on an x-axis table, which has a combination of rotary (y-axis) and linear (x-axis) movements of the tubing relative to the cutting laser beam. (abstract, figures, 0017, 0019, 0025, 0028, 0033)

McCoy discloses:

The present invention provides an improved system for producing metal stents with a fine precision structure cut from a small diameter, thin-walled, cylindrical tube. The tubes are fixtured under a laser and positioned utilizing a computer generated signal to move the tube in a very intricate and precise pattern around a linear and rotary axis. The stent is cut from small diameter tubing held between a collet and clamp, one of which is periodically opened and the other reciprocally moved to position a small length of tubing, sequentially beneath the cutting head. A water system is incorporated in the apparatus to remove debris falling into the interior of the cut tube and to push discrete portions of the cut tube (or stents) into a parts catcher to separate the stent from the uncut portion of the tube. (abstract)

...a gas jet stream substantially surrounds the laser beam where the beam impinges on the working outer tube surface to aid in cutting said tubing. (claim 7)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a laser directly and use a coolant as taught by McCoy in the Acciai et

Art Unit: 3742

al. apparatus and process because direct laser cutting while enhance efficiency and the coolant would yield greater precision because the debris would be removed during the laser machining.

It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time of the invention to place the stent and its associated "machining" debris at the bottom of the apparatus because this would negate contamination and possible damage to apparatus parts. For example this configuration would prevent chips from falling into motor windings and so forth.

Making elements integral was held to have been obvious. In re Wolfe 116 USPQ 443. Reversal of parts was held to have been obvious. In re Gazda 104 USPQ 400. Rearrangement of parts was held to have been obvious. In re Japikse 86 USPQ 70.

Acciai et al., Pacetti et al. and McCoy teach a laser and the use of water, but a water laser is not specifically taught.

Kranz discloses:

A stent...

In a preferred embodiment of a stent according to the invention the partition lines are of a width substantially corresponding to that of a clean incision when the surface is severed by means of a cutting beam, e.g. **a cutting jet of water preferably a laser beam**. Narrow partition lines give the non-expanded stent particularly high stability. (col. 2, lines 29-34)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a water/laser cutting jet as taught by Kranz in the Acciai et al. Pacetti

Art Unit: 3742

et al. and McCoy apparatus and process because it would ensure precision machining of the stent by removing cutting debris.

Claims 6 & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acciai et al., Pacetti et al., McCoy and (AAPA or Kranz), as stated above and further in view of Magnante (USPN 6,086,204)

Acciai et al., Pacetti et al. and McCoy teach a table/base, however, a granite base is not taught.

Magnante discloses:

...modified surfaces on contact lenses ... three dimensional contour cutting, laser ablation... (abstract)

...Correcting Surfaces on Lenses...

... Since the machine must be completely free of both internal and external vibrations, both lathe 30 and x-z slides 32 are secured to a pneumatically isolated table top 35 which rests on **granite base** 36. (col. 15, lines 44-45, 67 & col. 16, lines 25-27)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a granite base as taught by Magnante in the Acciai et al. Pacetti et al. and McCoy apparatus and process because it would ensure precision machining of the stent.

The type of materials chosen is a choice in design and substitution of known equivalent structures (table for granite) has been held obvious. In re Kuhle 188 USPQ (CCPA 1975), In re Ruff 118 USPQ 343 (CCPA 1958).

Response to Arguments

Applicant's arguments filed 5/7/09 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In this case, references are drawn to the machining of tubular materials (specifically stents).

Applicant argues that the water of McCoy cannot be introduced into the optical system of Acciai et al. The examiner respectfully disagrees because McCoy also uses a laser (i.e. optical) system.

Applicant argues that Acciai et al. and Pacetti et al. do not appear to be able to precisely position the stent. The examiner respectfully notes that precise position is not a claim limitation, but rather positioning. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., precision positioning) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Art Unit: 3742

Applicant argues that Pacetti et al. does not teach a rotary motor coupled to a linear motor wherein the rotary motor is positioned below the linear motor. the examiner respectfully notes that Pacetti et al. teaches a rotary motor (24) and a linear motor (28); with respect to positioning of the motors: It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time of the invention to place the stent and its associated "machining" debris at the bottom of the apparatus because this would negate contamination and possible damage to apparatus parts. For example this configuration would prevent chips from falling into motor windings and so forth. Thus the linear motor would positioned above the rotary motor which is directly attached to the stent. Reversal of parts was held to have been obvious. In re Gazda 104 USPQ 400. Rearrangement of parts was held to have been obvious. In re Japikse 86 USPQ 70.

Applicant argues that Kranz does not teach a laser-water jet. The examiner respectfully disagrees because, Kranz discloses:

A stent...

In a preferred embodiment of a stent according to the invention the partition lines are of a width substantially corresponding to that of a clean incision when the surface is severed by means of a cutting beam, e.g. **a cutting jet of water preferably a laser beam.** Narrow partition lines give the non-expanded stent particularly high stability. (col. 2, lines 29-34)

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Alexandra Elve whose telephone number is 571-272-1173. The examiner can normally be reached on 7:30-4:00 Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tu B. Hoang can be reached on 571-272-4780. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3742

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

August 7, 2009.

/M. Alexandra Elve/
Primary Examiner, Art Unit 3742